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(A) Decision on Patent Examination (Translation)

Date: March 7, Taiwanese Year 90 (2001)

Docket No.: (90) Jhi-Jan 2(5) 01059-Zu 09083004050

To: Mr. Jens Ponikau

Attorney : J. C. Chen, S. F. Lin

Address: 4F, 203 Ho-Ping E. Road, Sec. 2, Taipei, Taiwan

Int. Class: A61K 31/33

1. Application Number: 87117691
2. Title: Methods and Materials for Treating and Preventing Inflammation of Mucosal Tissue
3. Applicant: Jens Ponikau
Address: US
4. Attorney: J. C. Chen, S. F. Lin
Address: 4F, 203 Ho-Ping E. Road, Sec. 2, Taipei, Taiwan
5. Date of Application: October 26, Taiwanese year 87 (1998)
6. Priority Claims: 1997/10 28 60/063414 US
1997/10/28 60/063418 US
1998/04/28 60/083272 US
1998/05/22 60/086397 US
7. Name of the Examiner: S. S. YU
8. Decision of Examination:
Syllabus: This application should be rejected.
Basis: The first Clause of Section 1 and Section 2 of Article 20, Item 2
of Section 1 of Article 21, Sections 3 and 4 of Article 22, the Patent Law
Reasons : (To be continued)

(1) The subject invention, "Methods and Materials for Treating and Preventing Inflammation of Mucosal Tissue", uses a pharmaceutically active agent (such as amphotericin B, ketoconazole, and itraconazole) to treat allergic fungus-induced rhinosinusitis, i.e. related to non-invasive fungi in mucosal tissue, including airway, otitis media, and intestinal mucosities. However, it has been known that non-invasive fungi (such as *Alternaria*, *Aspergillus*, *Candida*, *Cladosporium*, and *Penicillium*, etc.) can induce rhinitis and asthma (Attachments #1 to #4) and cause diseases in the mucosal tissue (such as in the mouth, eye, ear, and skin) (Attachments #5 to #9). There prior art also shown amphotericin B, ketoconazole, itraconazole and/or sterol can be used to treat fungus-induced diseases (Attachments #10 to #23). Therefore, the subject invention can easily be made by people skilled in the art, and does not conform to patentabilities.

- (2) The method for treating a disease and the method for prophylactically treating a disease claimed in claims 1, 46, 47, 49, 50, 57, 58-62, and 64-69 are not patentable subject matter according to the Patent Law.
- (3) The article of manufacture comprising packaging material and a formulation claimed in claims 70-77 is lack of substantive technical characteristic and is not patentable.
- (4) The use claims of claims 78-106 are well known as mentioned above, and not patentable.
- (5) The formulation claims of claims 107-114 are well known as mentioned above, and not patentable.
- (6) The method of making an antifungal formulation of claim 115 is lack of substantive technical characteristic and is not patentable.
- (7) The method for culturing fungus of claim 116 are well known as mentioned above, and not patentable.
- (8) The method for obtaining a fungal antigen of claim 117 is lack of substantive technical characteristic of antigen and is not patentable.
- (9) The method for obtaining a fungal antigen of claim 118 is lack of substantive technical characteristic of antibody and is not patentable.
- (10) The pharmaceutical composition claims of claims 122-131 is lack of substantive technical characteristic and is not patentable.
- (11) The medication claims of claims 132-137 is lack of substantive technical characteristic and is not patentable.

In conclusions, the decision is made as syllabus under The first Clause of Section 1 and Section 2 of Article 20, Item 2 of Section 1 of Article 21, Sections 3 and 4 of Article 22 of the Patent Law because this application does not conform to patentability.

Commissioner (Seal)

In case of dissatisfaction with a denial of this Decision, a shortened statutory period for applying a Re-Examination by submitting two copies of statement of reasons and N.T.\$3500 is set to expire 30 days immediately following the date of receipt of the Decision.

(B) English Translation of Related Articles

Article 20:

An invention which may be put into industrial use shall be granted a patent provided that it is other than one:

1. Which, prior to the application for patent, has been published or put into public use. However, this provision shall not apply where such publication or use has been made for research or experimental purpose and application for a patent is filed within six months from the date of publication or use;

2.

3.

An invention not subject to any one of the situations listed in the preceding Paragraph shall still be denied a patent if it simply utilizes conventional technology or knowledge known prior to the application for patent and can easily be made by persons skilled in the art.

Article 21:

The following items shall not be granted an invention patent:

1. New varieties of animals and plants, except the cultivation and growth processes of new plant varieties;
2. Diagnostic, curing or surgical methods for diseases afflicting humans or animals;
3. Scientific theories or mathematical formulas;
4. Rules or methods of games and sports;
5. Methods or plans which can be implemented only by means of human reasoning and memory; and
6. An invention which is contrary to public order, good custom or sanitation...

Article 22

Application for a patent shall be made by the person entitled to file the patent application by submitting to the Patent Authority a written application together with a specification, drawings and an oath.

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The specification required under Paragraph one shall also contain, in addition to the claims of the invention, the prior art, the purpose of the invention, the technical description, characteristics and functions which would allow persons skilled in the art to understand the contents of and to practice the invention concern.

The claims to be contained in a patent application shall substantially describe the object of the patent application, technical contents and characteristics of the invention.

The method for preparing

正本

經濟部智慧財產局專利核駁審定書

受文者：傑斯·波尼考 先生（代理人：陳展俊

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地址：台北市和平東路二段二〇三號四樓

發文日期：中華民國九十年三月七日

發文字號：（九〇）智專二（五）01059字

第〇九〇八三〇〇四〇五〇號

一、申請案號數：〇八七一七六九一

分類：A61K 31/33

二、發明名稱：黏膜組織炎症的治療和預防的方法及物質

三、申請人：

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五、申請日期：八十七年十月二十六日

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六、優先權項目：

- 1 1997/10/28 美國60/063,414
- 2 1997/10/28 美國60/063,418
- 3 1998/04/28 美國60/083,272
- 4 1998/05/22 美國60/086,397

七、審查委員姓名：俞樹生 委員

八、審定內容：

主文：本案應不予專利。

依據：專利法第二十條第一項前段、第二十條第二項、第二十一條第一項第二款、第二十二條第三項、第四項。

理由：

(一) 本案所請為『粘膜組織炎症的治療和預防的方法及物質』，其係一種藥理活性化物(如兩性霉素B、酮康唑、伊曲康唑)具有治療過敏性真菌鼻竇炎(即與生活於粘膜內非侵襲性真菌有關)，包括呼吸道、中耳炎、腸道粘膜炎，惟已有相關前案揭示：非侵襲性真菌(如*Alternaria*、*Aspergillus*、*Candida*、*Cladosporium*、*Penicillium*...)可致鼻炎、氣喘(分別如附件一至四)及粘膜有關之疾病(如嘴、眼、耳、表皮)(分別如附件五至九)，且有先前技藝揭示兩性霉素B、酮康唑、伊曲康唑及/或類固醇具

有治療真菌引起之疾病（分別如附件十至二十三），故本案所請可為熟知該項技藝人士輕易達成者，不符專利要件。

（一）本案申請專利範圍第1、46、47、49、50、57、58至62、64至69項所請之「治療方法」、「診斷方法」，依專利法之規定，不予專利。

（三）申請專利範圍第70至77項所請之「包裝材料」、「配方製品」欠缺實質特徵，不符專利要件。

（四）申請專利範圍第78至106項所請之「應用」係屬習知（如上所述），故不符專利要件。

（五）申請專利範圍第107至114項所請之「配方」係屬習知（如上所述），故不符專利要件。

（六）申請專利範圍第115項之「製法」欠缺實質特徵，不符專利要件。

（七）申請專利範圍第116項所請之「培養真菌的方法」係屬習知（如上所述），故不符專利要件。

（八）申請專利範圍第117項所請之「培養真菌抗原的方法」欠缺抗原的實質技術特徵（如上所述），故不符專利要件。

（九）申請專利範圍第118項所請之「培養真菌抗體的方法」欠缺抗體之實質技術特徵（如上所述），故不符專利要件。

（十）申請專利範圍第122至131項所請之「藥用組合物」、欠缺實質特徵，不符專利要件。

（十一）申請專利範圍第132至137項所請之「藥劑」欠缺實質特徵，不符專利要件。



據上論結，本案不符法定專利要件，爰依專利法第二十條第一項前段、第二十條第二項、第二十一條第一項第二款、第二十二條第三項、第四項，審定如主文。

局長
陳明邦

依照分層負責規定授權單位主管決行

如不服本審定，得於文到之次日起三十日內，備具再審查理由書一式二份及規費新台幣參仟伍百元整，向本局申請再審查。